



Original Article

# Evaluation of an anti-snoring device featuring a Ni–Ti alloy elastic linkage in a simulated clinical environment



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Received 25 May 2025

Available online 12 June 2025

## KEYWORDS

Obstructive sleep apnea;  
Mandibular advancement device;  
Nickel-titanium alloy;  
Finite element analysis;  
Patient compliance

**Abstract** *Background/purpose:* Obstructive sleep apnea (OSA) is a common sleep-related breathing disorder that is often treated by mandibular advancement devices (MADs). However, conventional MADs are frequently associated with discomfort, rigidity, and limited patient compliance. This study aimed to design and evaluate a custom-made anti-snoring device featuring a nickel-titanium (Ni–Ti) alloy elastic connector to improve comfort, durability, and clinical performance.

*Materials and methods:* The device consisted of dual-layer upper and lower trays and was connected via Ni–Ti alloy rods. Finite element analysis (FEA) was conducted to compare the stress and deformation characteristics of three materials (Ni–Ti, stainless steel, and polycarbonate). Fatigue testing was also performed to simulate the long-term use. A clinical simulation involving seven adult participants diagnosed with mild to moderate OSA was conducted, including a seven-day trial and a post-trial questionnaire that evaluated comfort, fit, and effectiveness.

*Results:* FEA revealed that the Ni–Ti connector exhibited the most uniform stress distribution and the highest deformation capacity, indicating superior elasticity and resilience. Fatigue tests confirmed the structural stability after 5 million cycles. Subjective evaluations indicated

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the high user satisfaction and effective symptom relief; however, some discomfort related to oral dryness and temporomandibular joint (TMJ) pressure was reported.

**Conclusion:** The Ni–Ti-based anti-snoring device demonstrated favorable biomechanical properties and clinical usability. It offers a promising alternative to traditional MADs, potentially enhancing a long-term patient compliance and therapeutic outcomes. Further clinical validation is warranted.

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## Introduction

Obstructive sleep apnea (OSA) is a common sleep disorder worldwide, primarily caused by the collapse of the upper airway during sleep, leading to airflow obstruction. These results in recurrent episodes of apnea, accompanied by symptoms such as excessive daytime sleepiness and impaired concentration. Over the long term, OSA is associated with an increased risk of hypertension, cardiovascular disease, and stroke.<sup>1</sup> According to a report by the World Health Organization (WHO), approximately one billion adults globally are affected by this condition, with the highest prevalence observed in males aged 30–60 years.<sup>2</sup>

Common clinical treatments for OSA include continuous positive airway pressure (CPAP), surgical intervention, and oral appliance therapy (OAT). Among these, CPAP remains highly effective; however, its clinical utility is often limited by poor patient compliance and discomfort associated with the long-term use.<sup>3</sup> Surgical treatment, on the other hand, involves greater risks and higher costs. In contrast, oral appliances represent a non-invasive therapeutic alternative that advances the mandible to maintain airway patency and has gradually gained recognition from both patients and clinicians.<sup>4</sup>

Currently, available anti-snoring devices can be categorized into three main types: standard, electronic, and custom-made devices.<sup>5</sup> Standard devices include tongue-retaining and mandibular advancement types. While relatively affordable, these devices may not adequately fit individual anatomical variations, resulting in limited treatment efficacy.<sup>6</sup> Electronic anti-snoring devices utilize sound-sensing technology to detect snoring and deliver mild vibrations or other stimuli to prompt the user to adjust their sleeping position. Although typically more expensive, they are considered more comfortable and effective.<sup>7,8</sup> Custom-made devices are designed and fabricated based on individual assessments conducted by physicians, dentists, and dental technicians. Despite their higher cost, they offer improved comfort and therapeutic outcomes due to their precise fit to the patient's oral anatomy.<sup>9</sup> Commonly used materials in custom-made oral appliances include thermoplastic resin, silicone, and stainless steel.<sup>10</sup> However, the long-term use is often associated with issues such as discomfort, oral dryness, and increased pressure on the temporomandibular joint (TMJ). In addition, some devices' lack of flexible structural components limits their ability, limiting their ability to accommodate dynamic oral

movements, which may further reduce the patient compliance and overall therapeutic effectiveness.<sup>11</sup>

Therefore, this study proposed using a nickel-titanium (Ni–Ti) alloy known for its high elasticity and shape memory properties as the flexible connecting element in the design of an anti-snoring device. Due to its superelasticity, corrosion resistance, and excellent biocompatibility, Ni–Ti alloy has been widely applied in dental orthodontics and various medical devices,<sup>12</sup> and its potential for use in oral appliances has been increasingly recognized. The aim of this study was to develop a custom-made mandibular advancement device featuring a Ni–Ti elastic connector and evaluate its biomechanical properties, durability, and user experience through finite element analysis (FEA) and a simulated clinical trial. Furthermore, the stress analysis and user trials were conducted under simulated clinical conditions to evaluate the practical feasibility and performance of the proposed design.

## Materials and methods

### Device design and structural description

The anti-snoring device developed in this study is a mandibular advancement device (MAD) designed to reposition the mandible forward during sleep. Its innovative feature lay in using a nickel-titanium (Ni–Ti) alloy as a flexible connector, leveraging the alloy's shape memory and superelastic properties. The device consisted of upper and lower dental trays fabricated using a dual-layer material configuration: the outer layer was made of thermoplastic resin to provide structural rigidity. In contrast, the inner layer was composed of silicone to enhance comfort at the mucosal interface. The traditional elastic bands were replaced with pre-formed Ni–Ti alloy rods that functioned as elastic connectors, enabling adaptive mandibular advancement throughout the night. Each rod had a circular cross-section with a diameter of 0.07 inches and was shaped using orthodontic wire-bending techniques to match the desired geometry. A photograph of the fabricated device is presented in Fig. 1.

### Digital modeling and fabrication process

This study used a TRIOS 3 intraoral scanner (3Shape, Denmark) to capture three-dimensional images of the



**Figure 1** Design of the anti-snoring device proposed in this study.

participants' oral structures. The scanned data were converted into STL files, and digital models of the maxillary and mandibular arches were created accordingly. A photopolymerization-based 3D printer (Phrozen, Hsinchu city, Taiwan) was then employed to fabricate the dental models, with a layer resolution of 100  $\mu\text{m}$ , XY accuracy of 50  $\mu\text{m}$ , and a total printing time of approximately 1 h.

The main body of the anti-snoring device was thermo-formed using a pressure-forming machine (Biostar, Scheu-Dental, Iserlohn, Germany) at a pressure of 6 bar. The outer layer was fabricated using a 1 mm thick thermoplastic sheet, which complied with ISO 10993 biocompatibility standards. A soft silicone liner was applied to the inner surface to improve comfort during mucosal contact. Finally, the pre-formed nickel-titanium alloy connectors were installed, aligned, and assembled to complete the device.

### Finite element simulation and material comparison analysis

A comprehensive three-dimensional FEA model was developed in this study to evaluate the mechanical performance of different connector materials under realistic loading conditions. The model combined anatomical data with digitally generated parameters. The structural basis of the simulation was derived from mandibular bone images obtained via cone-beam computed tomography (CBCT) and combined with computer-aided design (CAD) based models of the upper and lower dental trays as well as the elastic connector components. The simulation evaluated the connector element using three different materials: Ni-Ti alloy, stainless steel, and polycarbonate. Material properties, including Young's modulus and Poisson's ratio, were sourced from published literature and applied accordingly (Table 1).<sup>13–15</sup>

This study referred to muscle stiffness parameters reported in the literature to define the mechanical boundary conditions. The stiffness of the masseter muscle and the posterior temporalis muscle was set at 16.35 N/mm and 13 N/mm, respectively.<sup>16</sup> Under the condition of 5 mm mandibular advancement, the corresponding tensile forces generated by these muscles were calculated to be 81.75 N and 65 N, respectively, resulting in a total force of 146.75 N. This combined force was applied in the anterior direction of the mandibular tray, while the maxillary tray was fixed to serve as the boundary condition.<sup>16,17</sup>

**Table 1** Finite element analysis (FEA) was used to simulate the mechanical behavior of three different materials.

| Materials       | Young's modulus | Poisson's ratio |
|-----------------|-----------------|-----------------|
| Ni-Ti alloy     | 45              | 0.33            |
| Stainless steel | 193             | 0.31            |
| Polycarbonate   | 3               | 0.38            |

Tetrahedral meshing was performed on the models of the dental trays and connector components, generating a total of 268,597 nodes and 74,030 elements. Evaluation metrics included von Mises equivalent stress distribution, total deformation, and localized strain concentration zones. These indicators were used to investigate the structural responses and potential failure risks of different materials under identical loading conditions.

In addition to static simulation, this study conducted dynamic fatigue testing to simulate the long-term clinical use and evaluate the anti-snoring device's durability and structural stability under repeated mandibular movements such as chewing and mouth opening/closing. The fatigue test was performed by ISO 7500-1 and ISO 4965 standards. The device was mounted on a universal testing machine (MTS Systems Corporation, Landmark 250 kN, Eden Prairie, MN, USA) and exposed to cyclic loading at a frequency of 14 Hz for a total of 5,000,000 cycles, representing the cumulative mechanical stress typically experienced over one year of nighttime use. Throughout the testing process, maximum and minimum load values were recorded, and the device was continuously monitored for signs of cracking, fracture, or structural failure. These observations served as the basis for evaluating the fatigue life and clinical safety. The test results were used as a critical indicator for verifying whether the Ni-Ti alloy connector design met the durability requirements for the clinical application.

### Participant recruitment and inclusion criteria

A total of seven adult participants, aged between 25 and 60 years, were recruited for the device-wearing trial. A specialist physician diagnosed all participants as having mild to moderate OSA, defined by an apnea-hypopnea index (AHI) between 5 and 30. Exclusion criteria included active periodontal disease, temporomandibular joint disorders, or complete edentulism. All participants provided the written informed consent prior to enrollment. The study protocol was reviewed and approved by the Research Ethics Committee of National Taiwan University Hospital (IRB No: 202403068RSPE).

### Simulated clinical use and operational procedure

A licensed dentist assisted participants with initial device fitting, adjustment, and training on the proper usage. They were instructed to wear the device continuously during nighttime sleep for a period of seven consecutive days. During the trial, participants were not allowed to receive any concurrent treatments related to sleep apnea, such as CPAP therapy or surgical intervention. Each participant was

required to maintain a daily log documenting their sleep conditions and any adverse responses during the device use, including symptoms such as oral dryness, masticatory muscle soreness, or breathing discomfort.

### Subjective evaluation questionnaire design

Upon completion of the trial, participants were asked to complete a structured questionnaire covering seven dimensions: wearing comfort, degree of oral dryness, perceived pressure on the TMJ, self-reported pain levels, time to fall asleep, device fit, and overall satisfaction. The questionnaire employed a five-point Likert scale for scoring and included reverse-coded items to minimize response bias. All questionnaire responses were collected and recorded anonymously.

### Statistical analysis

Statistical analysis was performed using SPSS 26.0 (IBM, Armonk, NY, USA). The Shapiro–Wilk test was first applied to assess the normality of the data distribution, as it was suitable for small sample sizes and effectively determines whether the data met the normality assumption. If the data followed a normal distribution, one sample t-test was conducted. Otherwise, the non-parametric Wilcoxon signed-rank test was used. Both tests evaluated whether participants' ratings differed significantly from a neutral reference value, thereby identifying directional tendencies in the subjective responses. In addition, descriptive statistics such as median and interquartile range were used to illustrate response distributions, supplementing the mean scores, which might be misleading in the presence of skewed data.

## Results

### Finite element analysis: stress and total deformation comparison

This study compared the mechanical performance of three different materials used in the connector structure of the anti-snoring device, focusing on von Mises stress and total deformation (Fig. 2). Under identical loading conditions, stainless steel exhibited the highest von Mises stress, reaching up to 310 MPa, while displaying the lowest total deformation of 0.009 mm/mm. Stress was notably concentrated at the junctions and bending points of the connector, indicating potential hotspots for the structural failure. Although stainless steel demonstrated the moderate overall deformation and did not fracture under load, it lacked elasticity and shape recovery capability, suggesting a risk of fatigue-related degradation over time that could impact user comfort and occlusal stability.

The Ni–Ti alloy showed the most uniform stress distribution without evident concentration zones. It exhibited a stress level of 220 MPa and the highest total deformation of 0.028 mm/mm, indicating excellent superelasticity and shape recovery characteristics. These properties contributed to the effective stress absorption and improved user compliance during wear.

The polycarbonate exhibited the lowest stress value at 140 MPa but still demonstrated relatively high total deformation at 0.021 mm/mm. In terms of total deformation, the polycarbonate showed significant bending and elongation, and the structural failure occurred at an applied force of 328.5 N. This finding suggests that the polycarbonate is unsuitable for applications requiring the dynamic loading resistance and the long-term structural stability. The comparative von Mises stress distributions and total deformations for each material are summarized in Table 2.

The Ni–Ti connector demonstrated a 35 % higher deformation capacity and a 29 % lower peak stress concentration under identical loading conditions than the stainless steel and the polycarbonate.

### Questionnaire results on wearing experience

A total of seven participants with mild to moderate OSA completed a seven-night trial of continuous nighttime device use, followed by a structured questionnaire evaluating their wearing experience and subjective outcomes in a clinical context. The questionnaire used a five-point Likert scale and assessed aspects including the device fit, comfort, localized discomfort, overall satisfaction, and perceived therapeutic effectiveness.

The device showed a statistically significant improvement in sleep apnea symptoms, with an average rating of 4.33 ( $P = 0.038$ ). Overall comfort and satisfaction were rated at averages of 3.67 and 3.83, respectively, indicating a generally positive user acceptance. However, certain aspects showed room for improvement, particularly oral dryness (average 2.0,  $P = 0.034$ ) and TMJ discomfort (average 2.33,  $P = 0.046$ ), which may be related to mandibular advancement design and the rigidity of materials used. These findings suggest that increased silicone buffering thickness can benefit future designs by enhancing comfort.

Other aspects, such as the gag reflex and mucosal soreness, received lower scores but did not reach statistical significance, indicating the minimal foreign-body sensation and the favorable clinical usability. Detailed questionnaire statistics are presented in Table 3. Overall, participants reported a high perceived treatment effectiveness, and their willingness for continued use was moderately high, supporting the preliminary clinical potential of the device design. Further refinements to improve comfort could enhance the long-term compliance.

## Discussion

Regarding the clinical suitability of elastic connector structures, in the design of this study, two types of elastic connector configurations-plate-type and wire-type-were evaluated for use in the anti-snoring device. Plate-type connectors have been widely adopted in previous oral appliance designs due to their ease of fabrication, predictable elastic modulus, and ability to provide initial structural support.<sup>18,19</sup> However, based on clinical simulation and material mechanics analysis conducted in this study, it was observed that plate-type connectors tended to develop stress concentration under dynamic occlusal

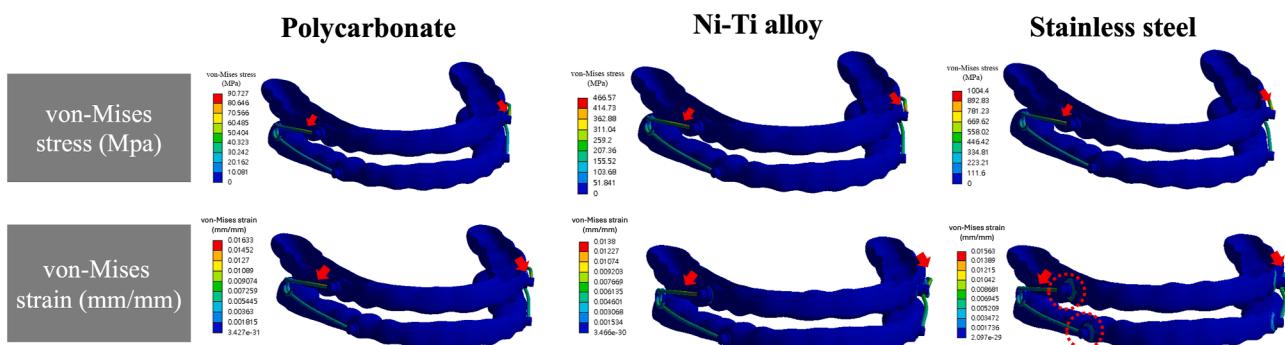


Figure 2 von-Mises stress and strain distributions of wire-type connectors made from Ni-Ti, stainless steel, and polycarbonate.

Table 2 Von-Mises stress and total deformation distributions of the three materials.

| Materials       | Stress (MPa) | Total deformation (mm) |
|-----------------|--------------|------------------------|
| Ni-Ti alloy     | 466.57       | 0.01227                |
| Stainless steel | 1004.4       | 0.01363                |
| Polycarbonate   | 1004.4       | 0.01452                |

Table 3 Questionnaire items and corresponding mean scores.

| Questionnaire item   | Mean $\pm$ SD   |
|--|-----------------|
| Degree of fit between the device and the teeth during wear                             | 3.00 $\pm$ 1.26 |
| Degree of contact between the device and the buccal (labial) mucosa during wear        | 3.17 $\pm$ 1.17 |
| Degree of gag reflex elicited while wearing the device                                 | 1.83 $\pm$ 0.98 |
| Perceived oral dryness while wearing the device  | 2.00 $\pm$ 0.63 |
| Self-reported temporomandibular joint (TMJ) discomfort during wear                     | 2.33 $\pm$ 0.52 |
| Comfort level associated with mandibular advancement while wearing the device          | 3.17 $\pm$ 0.75 |
| Self-reported mandibular bone discomfort during wear                                   | 2.17 $\pm$ 0.75 |
| Self-reported mucosal pain in the maxillary/mandibular region while wearing the device | 1.67 $\pm$ 0.52 |
| Perceived effectiveness of the device in alleviating obstructive sleep apnea symptoms  | 4.33 $\pm$ 0.82 |
| Overall satisfaction with the device during wear                                       | 3.83 $\pm$ 0.98 |
| Overall comfort while using the device   | 3.67 $\pm$ 1.03 |
| Willingness to continue using the device in the future                                 | 3.83 $\pm$ 0.98 |

loading, particularly at hooks or bending regions. These areas presented a potential risk for fatigue-induced structural failure or dislodgement.

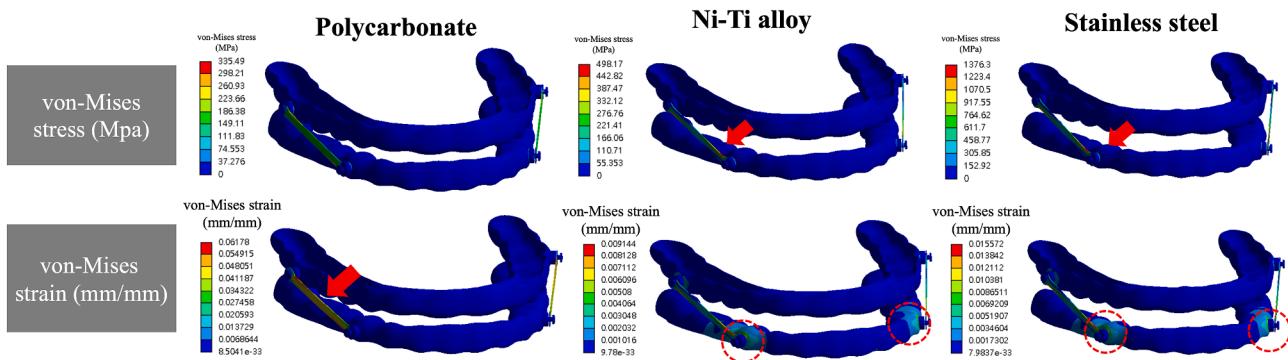
This finding suggests that although plate-type designs offer planar rigidity, they lack the flexibility and multi-axial

total deformation accommodation required to follow the complex mandibular movements involved in actions such as the mouth opening, rotation, and sliding. This observation aligned with the findings of Karacay et al.<sup>20</sup> Fig. 3 compares the stress and total deformation distributions of the plate-type elastic connectors.

Accordingly, when a Ni-Ti round wire characterized by the shape memory and super elastic properties is used as the elastic connector, it performs fundamentally differently from plate-type structures. The wire-type Ni-Ti element can produce stable and uniform deformation across multiple directions and rapidly return to its original form. This behavior indicates the superior total deformation adaptability, allowing the connector to absorb micro-movements and lateral forces that occur during sleep effectively. Such properties not only reduce the risk of stress concentration on the teeth or the TMJ but also provide the enhanced elastic buffering and user comfort throughout the wearing process. These characteristics are particularly advantageous for the prolonged and uninterrupted nighttime use.

Furthermore, from a biomechanical perspective, the recovery force generated by a wire-type connector under loading followed a nonlinear relationship, which more closely mimics the natural movement trajectory of the TMJ compared to the plate-type connectors.<sup>21,22</sup> This observation aligns with the findings of the present study. In simulated mandibular loading tests, the Ni-Ti wire connector was able to return to its original shape within 0.5 s after being subjected to forces exceeding 500 N. In contrast, the plate-type connector exhibited the structural failure under loads below 400 N, indicating a significantly lower tolerance and recovery capacity.

For the device longevity and durability, a dynamic fatigue test consisting of 5 million loading cycles was conducted to simulate the repetitive mechanical stress experienced during the routine daily use of the device. This loading cycle simulated approximately one year of nightly device use, supporting its potential long-term clinical durability. This corresponded to approximately one year of usage under typical conditions of 600–800 mouth opening/closing movements per day, with nightly wear lasting 6–8 h. Testing was performed using a universal testing machine, which showed that the failure occurred at a load of 669.758 N. Notably, no cracks or structural failures were observed in the elastic element under the high-frequency cyclic loading,



**Figure 3** von-Mises stress and strain distributions of plate-type connectors made from Ni-Ti, stainless steel, and polycarbonate.

indicating the excellent material durability and fatigue life. These results exceeded the predictions from finite element simulation, which estimated failure at 526.2 N, indicating that the actual mechanical performance of the Ni-Ti component may exceed the modeled predictions.

Many commercially available anti-snoring devices frequently encounter durability issues such as the fatigue fractures of metal hooks, deformation and loosening of plastic connectors, or the short lifespan of elastic materials.<sup>23</sup> As a result, users often require replacement parts or entirely new devices within a few months, increasing inconvenience and cost. In contrast, the Ni-Ti wire-based elastic connector significantly reduces the frequency of repairs and replacements, lowers the risk of accidental dislodgement during use, and meaningfully enhances user confidence and treatment adherence.

Moreover, the superelasticity of Ni-Ti alloy arises from its ability to rapidly transition between the austenite and martensite phases when stress is applied and subsequently removed.<sup>24,25</sup> This property enables the nonlinear deformation and recovery behavior, making it particularly well-suited for the long-term dynamic loading applications in oral appliances.

Regarding the clinical comfort and compliance analysis, although the Ni-Ti wire connector used in this study demonstrated the superior dynamic adaptability and shape recovery capabilities, the position of the anchoring points and the direction of applied forces might still impose the additional stress on the TMJ. Future device designs could incorporate the individualized adjustments based on pressure distribution simulations combined with intraoral scan data to address this. The potential enhancements include implementing adjustable silicone padding thickness, employing the dual-layer elastic support structures, or developing the micro-adjustable components tailored to variations in mandibular anatomy. Such modifications aim to optimize both the therapeutic effectiveness and user comfort.

In the questionnaire results, the items "oral dryness" and "TMJ discomfort index" received average scores of only 2.00 and 2.33, respectively. These were statistically significant based on the Wilcoxon signed-rank test ( $P > 0.05$ ), indicating that these two factors are the primary sources of discomfort reported by participants. Although mild discomfort was reported, the majority of participants expressed willingness to continue using the device, suggesting that these issues are tolerable and may improve with acclimatization. Complaints

related to oral dryness may reflect how the device affects salivary distribution and mucosal surface pressure during wear. This issue is particularly associated with the pressure-formed thermoplastic materials used in the outer layer, which are known to have the limited hydrophilicity and the poor heat dissipation. The prolonged contact with the buccal mucosa can lead to localized dryness and discomfort.<sup>26,27</sup> Additionally, the item measuring buccal mucosal contact received an average score of only 3.17, suggesting that some participants are still concerned about the fit and adaptation of the device to their oral tissues.

Regarding the TMJ response, although the device maintained mandibular advancement through the elastic connectors, misalignment between the anchoring force application points and the mandibular rotational axis may have resulted in asymmetric stress transmission, thereby increasing joint pressure.<sup>28</sup> The subjective ratings for mandibular protrusion awareness and TMJ pain during use were 2.17 and 2.33, respectively, indicating that the TMJ may not have fully adapted to the forward traction forces during the initial wearing period.

Additionally, the average score for the "gag reflex" was 1.83, suggesting that most participants experience only mild reactions; however, this may still influence the compliance in individuals with heightened oral sensitivity—particularly those using an anti-snoring device for the first time. These findings highlight the need for future structural refinements targeting the localized discomfort. Potential improvements include incorporating the micro-contoured cushioning surfaces, enhanced air-exchange channels, and using more hydrophilic materials to increase mucosal compatibility and overall comfort, thereby improving the clinical compliance.

This study successfully developed a customized mandibular advancement-type anti-snoring device incorporating a Ni-Ti alloy elastic connector. Through digital modeling, 3D printing, FEA, and clinical wear trials, the device was evaluated for its mechanical performance and user acceptability. The results suggest that the proposed device possesses favorable biomechanical performance and holds promise as a viable alternative to conventional anti-snoring devices. Future studies may consider expanding the sample size and conducting the long-term follow-ups to validate its clinical efficacy further. The integration of Ni-Ti connectors into MAD design offers a promising approach to improve the user comfort and treatment

compliance. Future studies with larger cohorts and polysomnographic measurements are warranted to validate the clinical efficacy.

## Declaration of Generative AI and AI-assisted technologies in the writing process

This manuscript didn't utilize AI and AI-assisted technologies during its preparation.

## Funding

This study was supported by the Metal Industries Research and Development Centre under grant No. 113-EC-17-A-22-1905.

## Declaration of competing interest

The authors have no conflicts of interest relevant to this article.

## Acknowledgments

None.

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